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TITLE: Online Early Resilience Intervention for Combat-Related PTSD in Military Primary Healthcare Settings: A Randomized Trial of "DESTRESS-PC"

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| <b>13. SUPPLEMENTARY NOTES</b>   |                         |                                 |   |  |
| <b>14. ABSTRACT</b><br>Over the course of the last year, the remaining two DESTRESS Nurses (at the WAMC and Charleston VA/Goose Creek sites) were hired, and other preparations were made for recruitment to begin at those sites--clinical space was obtained for the nurses, they completed 15 hours of DESTRESS website, nurse manual, and clinical assessment training, and they became credentialed at their respective sites to perform the duties of the study. The study Principal Investigator, COL Charles Engel, administered a PTSD training and study orientation for both the WAMC clinics (Joel, Clark, Robinson, and Family Medicine) and the Charleston VA/Goose Creek clinics with help from the respective site Principal Investigators and DESTRESS Nurses. Recruitment (which had begun at the Savannah, GA site in July of 2008) continued, and the first participant was consented and randomized in September. Recruitment began at the WAMC and Charleston VA/Goose Creek study sites in late 2008, bringing recruitment to full capacity. During the 7 months that recruitment has been underway at all sites, we have worked to maximize recruitment in order to make up for the delayed start of the study (which resulted from administrative issues relating to the study's dual funding). We have successfully instituted several strategies to boost study recruitment, and we are seeing a steady increase in the rate of participant enrollment, particularly at the Savannah, GA site, which has been up and running the longest. We are currently enrolling 1-2 participants per week, and expect the rate of recruitment to increase, allowing us to enroll approximately 121 participants by July 2010. Overall, we have consented 57 participants and randomized 25--12 at Savannah, 9 at WAMC, and 4 at Charleston VA/Goose Creek. |                         |                                 |   |  |
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## INTRODUCTION:

This randomized controlled trial will compare a cognitive-behavioral online self-management intervention (DESTRESS-PC) designed for primary care-delivered treatment of war-related PTSD to a control intervention, “optimized usual primary care PTSD treatment”. Optimized usual primary care will consist of PTSD diagnosis and referral back to the soldier’s primary care provider (PCP) followed by usual PCP guided treatment. Participants in both conditions will have scheduled check-ins with a study nurse to monitor their progress. The long term objective of the proposed research is to: 1) improve the readiness and resilience of military personnel who have symptoms from recent combat-related stressors; and 2) empower military primary care providers to assist personnel with PTSD symptoms following combat operations.

We expect that DESTRESS-PC will significantly decrease anxiety, depression, and physical symptoms, and improve overall health and occupational functioning relative to the optimized primary care condition. If this research project is successful, a provider-efficient model of care could be instituted in all DoD and VA primary care settings. By increasing the presence of available and effective PTSD treatment delivered in a primary care clinic with online psycho-education and therapeutic interventions, fewer military personnel will develop chronic PTSD. This is expected to improve the overall health of our patients and increase the military readiness of our service men and women.

## BODY:

Over the last year of the study, we have completed Task 2 (“Hire nurse managers and train nurse managers and clinic staff”) and have continued Task 3 (“Conduct study”), as laid out in the Statement of Work. In terms of specific accomplishments relating to Task 2, we re-hired a nurse for the Womack Army Medical Center (WAMC) site (after our initial hire was unable to obtain credentials to work at a DoD Healthcare facility) in late September 2008 and hired a nurse for the Charleston VA/Goose Creek site in October 2008. Both nurses completed 15 hours of DESTRESS website, nurse manual, and clinical assessment training, and became credentialed at their respective sites to perform the duties of the study. The study Principal Investigator, COL Charles Engel, administered a PTSD training and study orientation for both the WAMC clinics (Joel, Clark, Robinson, and Family Medicine) and the Charleston VA/Goose Creek clinics with help from the respective site Principal Investigators and DESTRESS Nurses.

In terms of specific accomplishments relating to Task 3, we have actively continued with participant recruitment, which began in July 2008 at the Savannah, GA site (one of 2 Charleston VA sites). We reached full scale when the other 2 sites (WAMC and Charleston VA/Goose Creek) were launched in late 2008. Thus, recruitment at all sites has been underway for approximately 7 months, and during that time, we have worked to maximize our recruitment numbers (see below) and have experienced a steady rise in enrolled participants.

Recruitment for the study has been slower than expected to date primarily because of a delayed startup as a result of administrative issues related to dual funding from NIMH and DoD. We have successfully instituted several strategies to boost study recruitment and this is paying dividends with an upward enrollment trajectory, particularly at our most mature site, Savannah GA. Thus far, we have: (1) added primary care clinics to the recruitment sites—we are now recruiting from all 4 primary care clinics at the Fort Bragg site (increased from 2) and are recruiting from 3 Charleston VA clinics (increased from 2); (2) worked with clinicians at the recruitment sites to streamline the study referral process and have brainstormed additional avenues for giving the DESTRESS Nurses access to large numbers of potential participants (e.g., obtaining databases of potential participants from referring physicians and having the RESPECT-Mil Care Facilitators at Ft. Bragg routinely brief patients they are following regarding the opportunity for study participation); (3) loosened some inclusion/exclusion criteria to allow more patients to qualify (i.e.: a) Reduced period of stable medication use from two months to one month, b) Changed exclusion for “engagement in specialty mental health care within last 2 months” to “engagement in specialty mental health care within last one month.”, c) Revised exclusion for “engagement in specialty mental health care” to “engagement in trauma-focused PTSD treatment at a frequency of twice a month or more (either group or individual; this also includes research study participation where this type of therapy

is used).”, d) Clarified exclusion for mood stabilizing or antipsychotic medications to exclude patients taking mood stabilizers or antipsychotic medication for Bipolar Disorder or any disorder with psychotic features, and e) Changed inclusion criterion for OIF/OEF Veterans to allow inclusion of all Veterans of south west Asian conflicts); (4) added more recruitment materials, including a flyer for providers to refer patients, and a general study flyer, a tri-fold study brochure, and a poster for patients to use to get information about the study, and (5) held more frequent clinic staff briefings and updates to remind them to refer potential participants. Changes 2 and 3 above were recently instituted, and we expect to see a large impact of these changes on recruitment in the coming weeks. We are currently enrolling 1-2 participants per week, and expect the rate of recruitment to increase, allowing us to enroll approximately 121 participants by July 2010. Overall, we have consented 57 participants and randomized 25—12 at Savannah, 9 at WAMC, and 4 at Charleston VA/Goose Creek (see Figures 1-4 on pages 3-4 under Supporting Data).

#### KEY RESEARCH ACCOMPLISHMENTS:

There are not yet any clear scientific findings resulting from this research because recruitment and data collection are still underway. The most recent analysis of baseline statistics, which was prepared for the bi-annual Data Safety Monitoring Board (DSMB) meeting, is summarized in Table 1 on page 5 under Supporting Data.

#### REPORTABLE OUTCOMES:

An abstract was submitted to the Mental Health Research Forum and a presentation will be given at that conference in September, 2009.

#### CONCLUSION:

There are no conclusions to report, as recruitment and data collection are still underway.

#### REFERENCES:

Litz, BT, Williams, L, Wang, J, Bryant, R, Engel, CC (2004). A therapist-assisted internet self-help program for traumatic stress. *Professional Psychology: Research and Practice*, 35, 628-634.

Litz, B, Engel, CC, Bryant, R, Papa, A (2007). A randomized, controlled proof of concept trial of an internet-based therapist-assisted self-management treatment for PTSD. *American Journal of Psychiatry*, 164, 1-8.

Kuehn, BM (2008). VA, military seek office-based PTSD care. *JAMA*, 299, 1885-1886.

#### APPENDICES:

N/A

#### SUPPORTING DATA:

See Figures 1-4 and Table 1 on pages 3-5.

Figure 1:

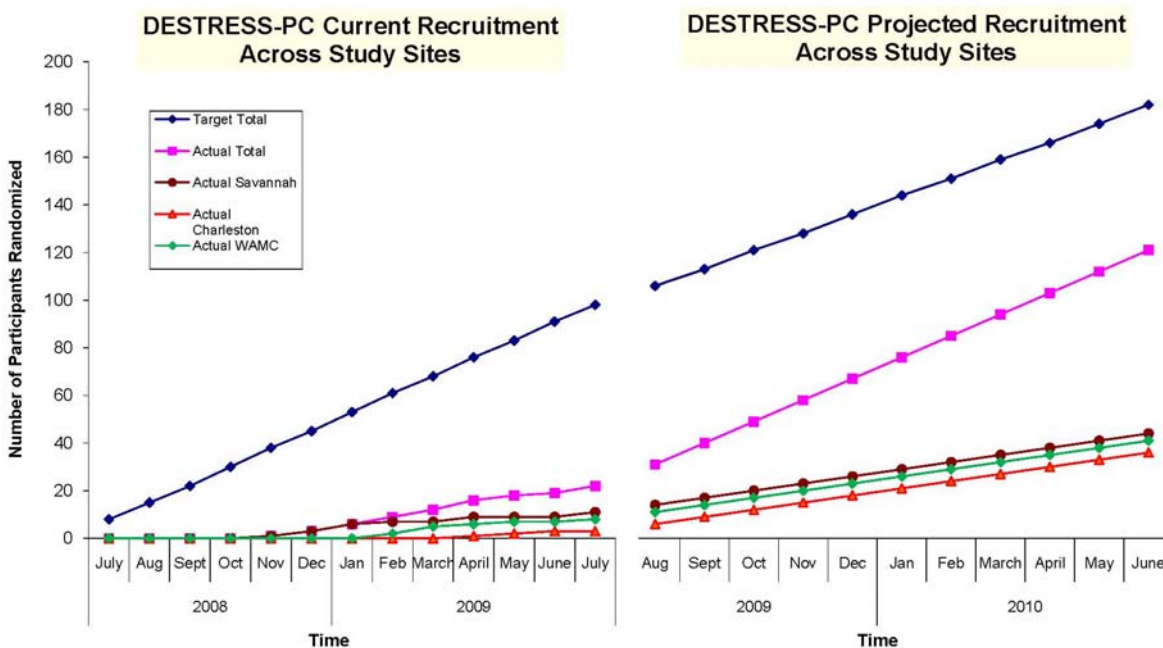


Figure 2:

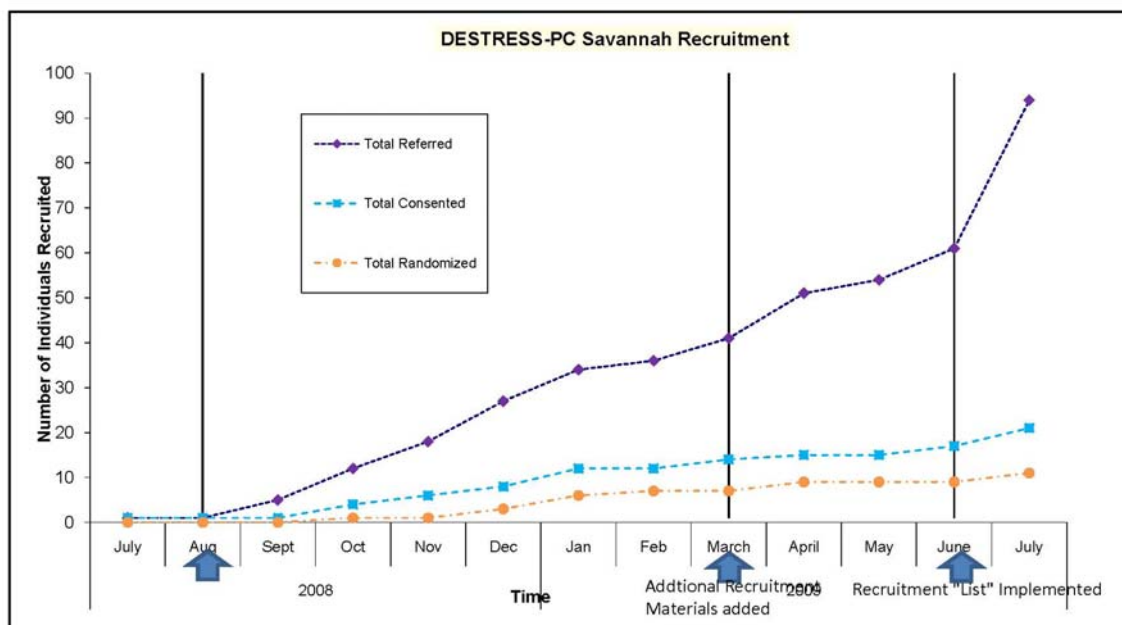


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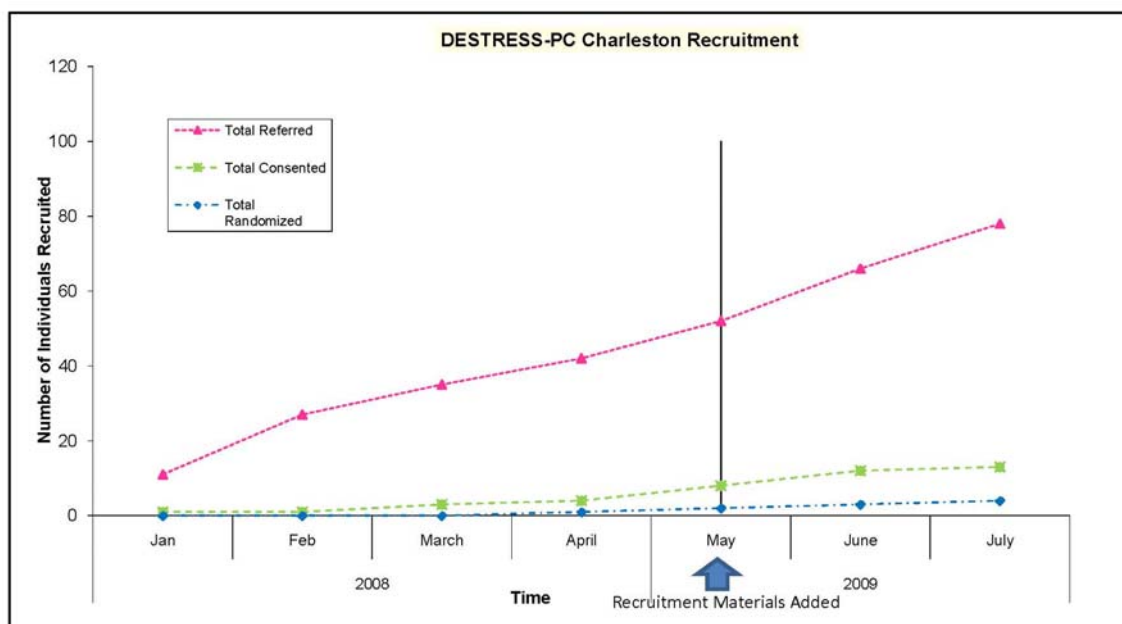


Figure 4:

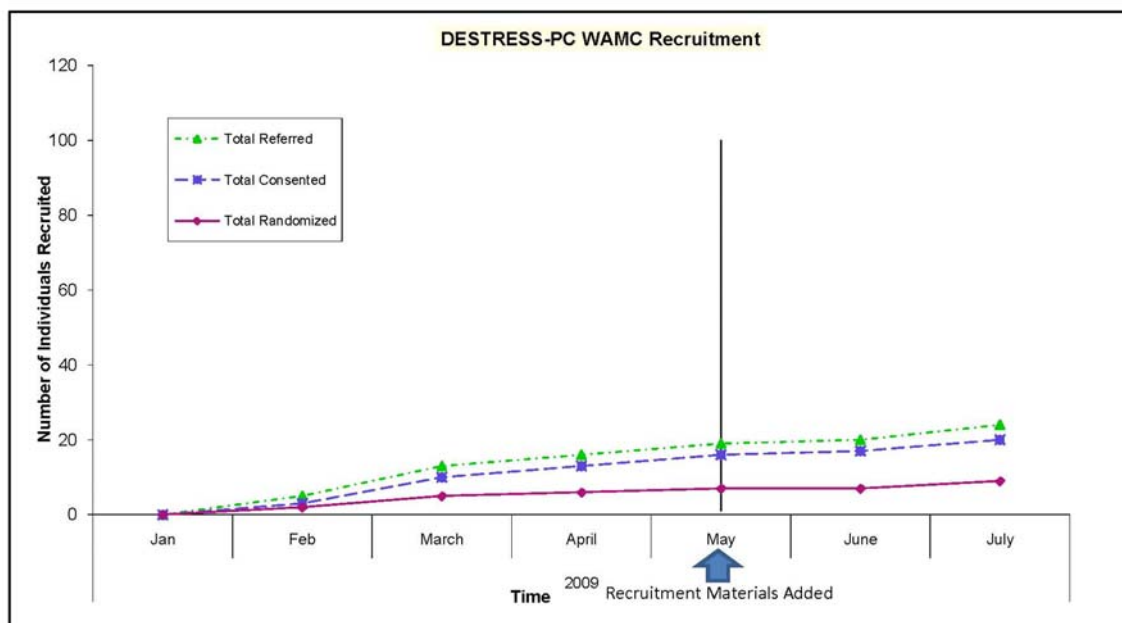


Table 1. Baseline Statistics

|                        |      |  |  | <u>Control</u> |        | <u>Treatment</u> |       |
|------------------------|------|--|--|----------------|--------|------------------|-------|
| Sample Size            |      |  |  | 9              |        | 10               |       |
| Male                   |      |  |  | 7              | (78% ) | 8                | (80%) |
| <u>Ethnicity</u>       |      |  |  |                |        |                  |       |
| Caucasian              |      |  |  | 5              | (56%)  | 6                | (60%) |
| African-American       |      |  |  | 3              | (33%)  | 3                | (30%) |
| Hispanic               |      |  |  | 1              | (11%)  | 1                | (10%) |
|                        |      |  |  | <u>Control</u> |        | <u>Treatment</u> |       |
|                        |      |  |  | <u>Mean</u>    |        | <u>SD</u>        |       |
| PCL                    | 50.7 |  |  | 0              | 11.3   | 4                | 59.5  |
| PHQ8                   | 19.0 |  |  | 0              | 04.2   | 9                | 21.5  |
| PHQ15                  | 25.7 |  |  | 0              | 03.7   | 7                | 27.4  |
| Physical functioning * | 63.0 |  |  | 0              | 29.8   | 3                | 67.5  |
| Energy/ fatigue *      | 39.0 |  |  | 0              | 12.4   | 3                | 41.5  |
| Emotional well-being * | 49.2 |  |  | 0              | 11.4   | 8                | 46.0  |
| Social functioning *   | 58.7 |  |  | 5              | 18.6   | 8                | 46.2  |
| Pain *                 | 5    |  |  | 7.00           | 2      | 2.17             | 5     |
| General health *       | 51.5 |  |  | 0              | 27.6   | 9                | 52.5  |
|                        |      |  |  |                |        |                  | 0     |
|                        |      |  |  |                |        |                  | 09.3  |
|                        |      |  |  |                |        |                  | 05.6  |
|                        |      |  |  |                |        |                  | 07.3  |
|                        |      |  |  |                |        |                  | 28.7  |
|                        |      |  |  |                |        |                  | 14.1  |
|                        |      |  |  |                |        |                  | 17.2  |
|                        |      |  |  |                |        |                  | 38.6  |
|                        |      |  |  |                |        |                  | 3     |
|                        |      |  |  |                |        |                  | 26.1  |
|                        |      |  |  |                |        |                  | 7     |

\* A higher score defines a more favorable health state.